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Description

A method and related capsule filling machine for producing sealed capsules

Technical Field

The present invention relates to a method and the related capsule filling machine for producing sealed capsules.

In particular, the present invention can be advantageously applied to the production of hard gelatin capsules of the type with lid and body which contain pharmaceutical material in powder or solid form, such as tablets, microtablets, pellets and the like, or in liquid form, and which the present specification expressly refers to but without restricting the scope of the invention.

Background Art

The operation of a modern capsule filling machine basically consists of a sequence of steps comprising the following main steps: a step of opening the closed empty capsules at a station where the capsule bodies are separated from the lids to form two separate rows of bodies and lids; a step of filling a dose of pharmaceutical material into each capsule body at a dosing station; and a step of closing the filled capsule by applying a lid to the respective body.

Once closed, the capsules are individually checked at an appropriate inspection and weighing station and, finally fed out of the machine into an appropriate container.

A more and more frequent requirement is for pharmaceutical capsules made in the above manner to also be sealed, which involves another step in their manufacturing process to be applied after the capsules have been closed. Sealing is designed not only to ensure that the pharmaceutical material, especially if liquid, does not leak out through the connection between capsule lid and body but also to prevent the risk of fraudulent tampering with, or undetected adulteration of, the capsules.

At present, there are several different methods of making

this seal. These can be divided broadly into two main types.

According to a first type, the entire outside surface of each capsule is provided with a sealing coat, as described, for example, in International patent WO 02/060372.

5           In this method, a predetermined quantity of capsules made in a capsule filling machine are collected in a rotary drum and then sprayed with a sealing substance such as an organic solvent (for example, an aqueous ethanol solution) to create a sealing coat which is completed by a substantially simultaneous step of drying  
10          the coat while the capsules are still inside the drum.

This method, although it provides satisfactory results, has the drawback of necessitating the use of the rotary drum in addition, obviously, to the capsule filling machine in which the capsules themselves are made.

15          According to a second type, sealing is accomplished by applying the sealing liquid (organic solvent or other equivalent substance) only at the discontinuous outside portion of the capsule defining the joint between the lid and the body once the two parts have been securely fitted to each other.

20          In a known solution implementing this type of method, each individual capsule is sprayed (or, more generally, coated) with the sealing liquid in a self-contained sealing machine to which the full, closed capsules are fed by the filling machine that has made them.

25          This second type of method is also embodied in two different constructional solutions described in US patents 4,793,119 and 5,094,184.

30          In these solutions, the perfectly closed, full capsules are transferred individually on appropriate conveyors from the capsule filling machine to a sealing machine of the type comprising a station for horizontally positioning each single capsule.

35          According to the above mentioned United States patents, each capsule is moved into contact with a sealing roller, which is partially immersed in a tank containing the sealing substance, and rotated about its longitudinal axis in such a way that the roller applies a "band" of the sealing substance to the joint between the lid and the body. This outside sealing band is then dried at a

subsequent drying station.

These methods of externally sealing a restricted area of the capsules, however, have considerable drawbacks.

Thus, in the first of the above mentioned solutions, it is  
5 not possible to control the uniformity of sealing substance  
distribution, which means there is no guarantee of creating an  
effective seal. The relative position between spray nozzle and  
capsule makes it necessary to spray an excessive quantity of  
sealing substance, with the risk of the substance dripping onto  
10 parts of the machine and damaging the machine or, at best,  
requiring frequent maintenance and cleaning.

The second of the solutions described above has the drawback  
of reducing productivity since the steps of transferring the  
capsules from the filler and positioning them on the conveyors  
15 require time, added to the fact that the passage of the individual  
capsules over the drums is necessarily slow in order to correctly  
distribute the sealing substance.

Furthermore, both the solutions described above involve  
handling the individual capsules already made as they feed out of  
20 the capsule filler towards another machine which, besides slowing  
down production, as already mentioned, creates the added risk of  
leakage of product from the capsules before they are sealed,  
especially if the material inside the capsules is liquid.

The aim of the present invention is therefore to overcome  
25 the considerable drawbacks of prior art.

More particularly, the main aim of the invention is to  
create perfectly sealed capsules of the lid and body type by a  
quick and sure process performed inside the same machine that  
fills and closes the capsules themselves, thus eliminating the  
30 need not only for additional sealing apparatus outside the capsule  
filler but also for the complex handling apparatus required to  
feed the capsules to the external sealing apparatus without  
damaging them.

### 35 Disclosure of the invention

The present invention accordingly provides a method for  
producing sealed capsules, each defined by a body coupled with a

lid, the method at least comprising the steps of filling the capsule body with a quantity or dose of material and closing the capsule by placing the lid over the body so that their respective annular ends overlap; the method being characterised in that it  
5 further comprises a step of applying a sealing substance to at least one of the overlapped ends of the capsule body and lid, said sealing step being performed before the capsule is closed.

The present invention also relates to a capsule filling machine for the production of hard gelatin capsules of the type  
10 with lid and body containing pharmaceutical material, the machine being of the type comprising a station for feeding the capsule bodies and lids; a dosing station for filling a dose of the material into each capsule body; and a station for closing the capsules by placing each lid over the respective body so that  
15 their respective annular ends overlap; the machine being characterised in that between the dosing station and the closing station there is at least one intermediate operating station for applying a sealing substance to the capsule lids and bodies in the vicinity of their ends.

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#### Description of the drawings

The technical characteristics of the invention, with reference to the above aims, are clearly described in the claims below and its advantages are apparent from the detailed  
25 description which follows, with reference to the accompanying drawings which illustrate a preferred embodiment of the invention provided merely by way of example without restricting the scope of the inventive concept, and in which:

- Figure 1 schematically illustrates the sequence of steps applied to a capsule of the type with lid and body and constituting the method according to the present invention;  
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- Figure 2 is a top plan view with some parts cut away for clarity, of a capsule filling machine implementing the method according to the invention for making sealed capsules;

35 - Figure 3 is a side view, partly in cross section and with some parts cut away for clarity, of an operating area of the capsule filling machine of Figure 2;

- Figure 4 is a side view, partly in cross section and with some parts cut away for clarity, of another operating area of the capsule filling machine of Figure 2;

5       - Figure 5 is a side view, partly in cross section and with some parts cut away for clarity, of yet another operating area of the capsule filling machine of Figure 2;

- Figure 6 is a front view, partly in cross section and with some parts cut away for clarity, of yet another operating area of the capsule filling machine of Figure 2.

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Detailed description of the preferred embodiments of the invention

Figure 1 schematically illustrates, in two different variants, the sequence of steps constituting the method according to the present invention for making sealed capsules C of the type with lid  
15       2 and body 1 coupled to each other in such a way that their ends 1a and 2a overlap and containing preferably but not exclusively pharmaceutical material in liquid or powder form, whilst Figures 2 to 6 illustrate a capsule filling machine 4 that implements said method.

20       The method illustrated in Figure 1 comprises the steps (performed according to the direction K) of filling the body 1 of each capsule C with a dose 3 of pharmaceutical material (arrow F3), applying a sealing substance to at least one of the ends 1a, 2a of the body 1 and lid 2 to be overlapped, and then closing the  
25       capsule C by moving the body 1 and the lid 2 together in such a way that the lid 2 overlaps the body 1 (arrows F100), thus simultaneously closing and sealing the capsule C.

30       The empty capsules C are closed when they are fed into the machine at the start of the process. Before they can be filled, they must be opened by moving the body 1 and the lid 2 apart to separate them (arrows F101 in Figure 1).

As illustrated in Figure 1, the step of applying the sealing substance is performed before the step of closing the capsule C is completed.

35       In particular, the step of applying the sealing substance is performed during or immediately after, the partial overlapping of the lid 2 over the body 1 at the ends 1a and 2a and while the body

1 is rotated about its longitudinal axis Z in such a way that the sealing substance is applied to the circular end 1a of the outside surface of the body 1 (arrows F102, Figure 1).

Alternatively, the step of applying the sealing substance is performed during or immediately after, the partial overlapping of the lid 2 over the body 1 at the ends 1a and 2a and while the lid 2 is rotated about its longitudinal axis Z in such a way that the sealing substance is applied to the circular end 2a of the outside surface of the body 1.

Preferably, the step of applying the sealing substance is performed while both the full capsule body 1 and the lid 2 are rotated about the longitudinal axis Z during or after the partial overlapping of the body 1 itself, in such a way that the sealing substance is applied to the circular ends 1a and 2a of the outside surfaces of both the body 1 and the lid 2.

Another way of applying the sealing substance is to rotate the capsule body 1 and lid 2 about the longitudinal axis Z and simultaneously moving the body 1 and lid 2 towards each other along the longitudinal axis Z in such a way as to join them and thus close the capsule C (as indicated by the arrows F100 in Figure 1).

The sealing substance is applied preferably by spraying and consists of a mixture of different substances depending on operating requirements and on the type of capsule C, whose body 1 and lid 2 are usually made from hard gelatin.

The sealing substance normally used is an aqueous mixture of water and ethanol or the like or a cellulose based liquid substance or a liquid substance based on gelatin of the same type as the one which the lid 2 and body 1 are made of.

The step of closing the body 1 and lid 2 is followed by a step of drying the sealing substance while the capsule C is held firmly in the closed position so as to eliminate or minimise the risk of dripping or leakage of the material from the capsule C.

Preferably, the drying step is performed while the sealed capsule C is transferred and fed out towards capsule collection stations.

As better illustrated in Figure 2, a capsule filling machine

4 for making the sealed capsules C described above essentially comprises the same operating units as a customary capsule filling machine for making capsules C, that is to say, a station 5 for feeding the bodies 1 and lids 2, a dosing station 6 for filling the material into the bodies 2, and a station 7 for closing the capsules C by placing the lid 2 of each capsule C over the respective body 1 so that their respective ends 1a, 2a overlap.

The stations 5, 6 and 7 are not described in detail and are only partly illustrated in Figures 2 to 6 since they are of known type.

In particular, the feed station 5 feeds preferably closed, empty capsules C and opens them in a known manner (not illustrated) before they reach the dosing station 6.

In addition to the above mentioned stations, the machine 4 also comprises a station 40 for detecting the presence of the bodies 1 and lids 2 and a station 41 for selecting reject capsules C.

As better illustrated in Figures 2 to 5, between the dosing station 6 and the closing station 7, there is a new intermediate station 8 where the bodies 1 and lids 2, whose ends 1a and 2a are already partially overlapped, are precoupled to each other and a sealing substance is applied to the overlapping area between the body 1 and lid 2.

More specifically, the intermediate station 8 comprises, in succession, a station 9 for precoupling the capsule body 1 and lid 2 to each other, a substation 10 for applying the sealing substance and the aforementioned closing station 7.

As shown in Figure 2, the machine 4 comprises a first capsule C handling turret 11 that rotates with preferably continuous or alternating motion along a circular path P that enables the capsules C to be fed to the aforementioned feed, opening and dosing stations 5 and 6, and a second rotating turret 12 constituting the aforementioned intermediate station 8 as well as the closing station 7.

The second turret 12, which is independent and rotates about its axis Z', is designed to position the capsules C at the precoupling substation 9, at the substation 10 for applying the

sealing substance and at the closing station 7 along another circular path P1 (Figure 2).

The second turret 12 is equipped with a plurality of means 13 for retaining respective capsules C, mounted radially on the second turret 12 and acting in conjunction with means 14 for handling the body 1 and lid 2 forming each capsule C.

For convenience, the description below refers to the formation and sealing of a single capsule C but it may obviously be extended to groups of capsules C.

As shown in Figures 3 to 6, the retaining means 13 comprise, for each capsule C, a concave end seat 13a located on the second turret 12.

The seat 13a accommodates the capsule body 1 and lid 2 and has a central cavity 13b for separating two portions of the seat 13a and having leading into them respective radial conduits 16 and 17 connected to second means (represented by a block 18 in the drawings) for creating a vacuum which enable them to retain the portion of the respective body 1 and lid 2 when the body 1 and lid 2 themselves move to the substations 9 and 10 and to the closing station 7.

The above mentioned handling means 14 are located in the vicinity of the retaining means 13, move vertically in both directions and are equipped with first means 15 for creating a vacuum (also represented by a block in the drawings) which enable the following steps to be carried out, respectively, along the rotational path P1 of the second turret 12: picking up and transferring the body 1 and lid 2 from the first turret 11 to the second turret 12, with the body 1 and lid 2 themselves preliminarily positioned in such a way that they partially overlap each other, that is to say, with their ends 1a and 2a in contact at the retaining means 13 (Figure 3); rotating the capsule body 1 and lid 2 at the substation 10 for applying the sealing substance in such a way as to spread the sealing substance evenly along a closed annular surface of height S at the overlapping area (Figure 4); and closing the capsule C by moving the body 1 and lid 2 closer together (Figure 5).

More specifically, the handling means 14 may differ

according to the positioning and handling operations they are required to perform.

At the precoupling substation 9 (Figure 3), the handling means 14 (Figure 3) comprise a pair of hollow cylindrical pins 19 and 20 located on opposite sides of the second turret 12.

The two pins 19 and 20 are equipped with the aforementioned first means 15 for creating a vacuum in order to hold the body 1 and lid 2, and with handling means 21 (arrows F21) for enabling stable contact, on both sides, with the body 1 and lid 2 positioned on the first turret 11 so as to transfer them (arrow F12) to the second turret 12 while partially overlapping the body 1 and lid 2.

When the capsule body 1 and the lid 2 reach the seat 13a, the second vacuum means 18 hold the body 1 and lid 2 in a stable position so that the second turret 12 can be moved along the path P1.

At the sealing substation 10, the handling means 14 (Figure 4) comprise at least one cylindrical pin 22 for coming into contact with the bottom of the body 1 through the first vacuum means 15 and rotating the partly overlapped bottom 1 and lid 2 about the longitudinal axis Z with a force that is greater than the force exerted by the retaining means 13.

In other terms, still with reference to Figure 4, the cylindrical pin 22 is placed in contact with the bottom end of the body 1 and held by suction, while the portion of the second vacuum means 18 that hold only the lid 2 are momentarily turned off to enable the pin 22 to rotate the entire capsule C (arrow F22) while the sealing substance is applied (in the drawings, the parts where the vacuum is on are indicated by direction arrows).

The sealing substation 10 (Figure 4) comprises at least one spray nozzle 23 facing a capsule body 1 and lid 2 as they are rotated by the second turret 12.

The nozzle 23 is positioned at the overlap between the body 1 and lid 2 so as to spray the sealing substance on the areas 1a and 2a uniformly while the body 1 and lid 2 are being rotated.

The position of the nozzle 23 relative to the body 1 and lid 2 causes the sealing substance to be sprayed on an annular band S

of the body 1 during rotation.

As illustrated in Figure 5, the handling means 14 at the closing station 7 comprise another pair of hollow cylindrical pins 24 and 25 positioned on opposite sides of the second turret 12.

5       The two pins 24 and 25 are equipped with the aforementioned first vacuum means 15 for holding the body 1 and lid 2, and with straight-line handling means 21 not only to enable stable contact with the body 1 and lid 2 on both sides but also to apply an opposite force on them (arrows F24 and F25) so as to fully close  
10       the capsule C by overlapping the body 1 and lid 2.

At least one of the pins 24 and 25 may also be equipped with rotational handling means 26 so as to impart a twisting movement to the capsule C while it is being closed, thus spreading the sealing substance more evenly on the overlapped areas (arrow F26).

15       The machine 4 further comprises a station 27 for drying and feeding out the capsules C, said station being located downstream of the closing station 7 on the circular path P1 (Figures 2 and 6).

More specifically, the drying and outfeed station 27 may  
20       comprise, for example, a capsule C conveyor belt 12 positioned in the vicinity of and under the second turret 12 for sealing and closing the capsules C.

The surface of the belt 28 has a plurality of seats 29 each designed to accommodate a single capsule C which can be  
25       transferred by the respective handling means 14 from the seat 13a to the seat 29 itself in a vertical direction V (see arrow in Figure 6) so that the capsule C remains in a stable position until it is expelled.

It will be appreciated that a capsule filling machine made  
30       in this way and implementing the method described above achieves the above mentioned aims because it enables the capsules to be sealed in the capsule filling machine itself before they are closed.

More specifically, the sealing method according to the  
35       invention brings considerable advantages thanks especially to the speed at which the sealing step is carried out without allowing the material, inside the capsules to leak out, producing perfectly

sealed capsules handled in optimum manner before being fed out of the capsule filling machine that implements the method itself.

Furthermore, since the capsules are filled, closed and sealed in the same machine, the space occupied by production is significantly reduced, which enables considerable savings.

In addition, the method according to the invention can be used with different types of sealing substances according to operating requirements depending, for example, on specified regulations or on the type of material used to fill the capsules.

It will be understood that the invention as described herein can be modified and adapted in several ways without thereby departing from the scope of the inventive concept. Moreover, all the technical details may be substituted by equivalent elements.